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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,762	10/22/2003	Bo Runeman	018798-164	6021
21839 7590 01/10/2008 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER OGDEN JR, NECHOLUS	
			ART UNIT	PAPER NUMBER
			1796	
			NOTIFICATION DATE	DELIVERY MODE
			01/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/689,762	Applicant(s) RUNEMAN ET AL.	
	Examiner Necholus Ogden	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-25, 27 and 29-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20-25, 27, 29-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-24-2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 21, 23 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The aforementioned claims as amended state that the lipid phase is "non-polar", however, applicant does not have support for this assertion. The lipid phase, according to applicant's specification requires that some components are polar and non-polar components but not all components are non-polar as claimed. Therefore, applicant

cannot assert that every component in the lipid phase is non-polar as amended.

Clarification and/or corrections are required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-18, 20-25, 27, 29-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (5,763,332) in view of WO (01/13596).
9. Gordon et al disclose a cleansing article such as wet-like wipe for personal cleansing (col. 1, lines 20-25), said article comprises a hydrophobic layer material which is a film formed of polyethylene or polypropylene. One surface of hydrophobic layer is treated with an emulsion. The other side of the layer is attached to the substrate. A second hydrophilic layer located on the emulsion layer to form a hydrophilic substrate (col. 4, line 63-65 and col. 5, lines 10-30, see figures 4 and 6). Gordon et al teach that numerous material are deposited on the hydrophobic substrate such as silicones and paraffins (col. 7, lines 22-40) and the internal phase emulsion comprises waxy lipids such as petrolatum (col. 12, lines 62); cleansing materials such as anionic, nonionic and cationic surfactants (col. 17, lines 45-65); and electrolytes including calcium chloride (col. 14, lines 20-24).
10. Gordon et al lack a specific teaching of lactobacillus plantarum.
11. WO '956 discloses a composition suitable for personal wipes (page 32, lines 17-26) comprising a lactic acid producing bacteria such as lactobacillus plantarum (page 12, line 30).
12. It would have been obvious to one of ordinary skill in the art to include the lactic acid producing bacteria to the wipes of Gordon et al because WO '956 teaches that said bacteria to aid in inhibiting the growth of bacterium, yeast, fungi and viruses (see abstract). Moreover, with respect to the water activity, the examiner asserts that said activity would have been inherent to the lactobacillus plantarum of WO '956 because

said lactobacillus would comprise this characteristic. With further respect to the colon forming units, Gordon et al teach applicant's lipids that are capable of forming said CFU as claimed. Therefore, one of ordinary skill in the art would have been motivated to include said lactic acid producing bacteria as an antimicrobial agent in said cleansing wipe products, in the absence of a showing to the contrary.

Response to Arguments

13. Applicant's arguments filed 10-24-2007 have been fully considered but they are not persuasive.

Applicant argues that Gordon requires an external lipid phase dispersed within an internal polar phase and the claims as amended require a non-polar lipid phase.

The examiner contends that Gordon teach a non-polar lipid phase as claimed, applicant's claims have a transitional phrase language of comprising and therefore do not exclude additional phases such as polar phases. Moreover, applicant has not demonstrated any criticality, commensurate in scope with the claimed language, to support his assertion that an internal polar phase would be harmful to the lactic acid.

Applicant argues that one of ordinary skill in the art would not incorporate the emu oil of WO '956 into the high internal phase emulsion compositions of Gordon et al as the lipid.

The examiner contends and respectfully disagrees because Gordon et al teach the use of lipids such as petrolatum (col. 12, lines 60-62) and WO '956 is relied upon only for the inclusion of an antimicrobial component such as a lactic acid producing bacteria. Again, in the absence of a showing, commensurate in scope with the claimed

invention, it would have been prima facie obvious for a personal cleansing wipe of Gordon et al to invite the inclusion of an antimicrobial lactic acid producing bacteria to aid in combating viruses and microbes as suggested by WO '956. Moreover, applicant's arguments are not substantiated by facts but instead are conclusory statements. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

14. Applicant argues that proper preparations have not been met regarding the water activity.

15. Again, the prior art of record teach each of the claimed ingredients in their requisite proportions in the analogous field as claimed. Therefore, a prima facie case of obviousness is presented and applicant should refute said case by showing in a Declaration or Affidavit that the water activity is not presented or prepared properly.

16. Applicant argues that the combination of Gordon et al and WO '956 has failed to suggest first and second parts are separate in different parts of said tissue.

The examiner contends that Gordon et al disclose two separate layers divided by a barrier layer and said layers comprise an emulsion phase with a cleansing component (see column 17, lines 45-65) and any additional component such as an antimicrobial

agent lactic acid bacteria would produce two different *parts* on separate layers divided by barrier as claimed.

17. Applicant argues that the limitations of first and second sheets joined together on opposite sides of the tissue as disclosed in claims 21 and 23 is not met.

18. The examiner contends and respectfully disagrees and invites applicant to figures 3 and 5 which disclose said limitations.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Necholus Ogden whose telephone number is 571-272-1322. The examiner can normally be reached on M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nicholas Ogden
Primary Examiner
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